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| 10/727,214 | 12/03/2003 | Wendelin Samstag | 1/1441 | 8889 |

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EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,214

Applicant(s)

SAMSTAG ET AL.

Examiner

Rebecca L. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/19/04, 12/3/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-9 are currently pending in the instant application. Claims 1-6 are rejected and claims 7-9 are withdrawn from consideration as being for non-elected subject matter.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-6, in the reply filed on 24 March 2006 is acknowledged.

Specification

The disclosure is objected to because of the following informalities: Specifically, morpholine is spelled incorrectly in the specification, see "mopolinin-4-yl" which should be --morpholin-4-yl—in all instances.

Appropriate correction is required.

Claim Objections

Claims 1, 4 and 5 are objected to because of the following informalities: the claims contain "mopolinin-4-yl" instead of --morpholin-4-yl—. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of the crystalline compound with the specific XRPD found on pages 5 to 7 of the specification,

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does not reasonably provide enablement for any polymorph of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is noted that claim 6 contains the x-ray diffraction pattern of “the pure polymorph” of (I), however, claims 1, 4 and 5 are not preparing “the pure polymorph” of (I) but “a polymorph” of (I). Therefore, claim 6 is also rejected.

As stated in the MPEP 2164.01 (a), “There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.”

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, the claims are read as a method for preparing any polymorph of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea , not just the specific crystalline form of 1-[tert-

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butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea with the XRD pattern as found on pages 5 to 7 of the instant specification. The phrase "a polymorph" in claims 1, 4 and 5 includes any polymorph of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea . Furthermore the phrase "characterized by" in claim 6 is considered open language and therefore can include peaks other than as found in the XRD pattern of the claim. Therefore, claims 1-6 are drawn to a process for preparing multiple polymorphs of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea when the specification only provides enablement for the process of preparing the specific crystalline form with the XRD pattern as found on pages 5 to 7 of the instant specification.

The nature of the invention

The nature of the invention is a process of preparing any polymorph of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea.

The state of the prior art and the predictability or lack thereof in the art

It is the state of the prior art that polymorphism is the existence of different solid forms (modifications) of a compound which have the same chemical composition but different structures and thus different physical and sometimes also chemical properties (Concise Encyclopedia Chemistry 1993). It is also the state of the art that any polymorph (including compounds that are characterized by the X-ray pattern in claim 6) of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea would include other forms without

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the specific X-ray diffraction pattern found on pages 5 to 7 of the instant specification. It is the state of the prior art that under any given pressure and temperature, other than the conversion points, only one modification is stable, the one with the lowest vapor pressure. Often the conversion rate in the solid phases is so slow that even modifications, which are unstable under the conditions, can be kept for a long time in their metastable state. This conversion rate can depend on the rate of temperature change or pressure change (Concise Encyclopedia Chemistry 1993). The predictability or lack thereof in the art is that there can be multiple forms of a solid in existence and these polymorphs are created by varying crystallization processes which began with varying starting materials, utilize varying solvents, varying temperatures and varying reaction times. There is no method that exists to predict the polymorphs of a solid compound with significant certainty (Rouhi, page 32). Furthermore, in addition to exhibiting polymorphism, many compounds form crystalline solvates in which the solvent molecule is an integral part of the crystal structure. Just as every polymorph has its one characteristic X-ray diffraction pattern, so does every solvate. (US Pharmacopia #23, page 1843) Also, sometimes the differences in the diffraction patterns of different polymorphs are relatively minor, and must be very carefully evaluated before a definitive conclusion is reached (US Pharmacopia, page 1843).

The amount of direction or guidance present and the presence or absence of working examples

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The only direction or guidance present for the instant process is the preparation of the specific crystalline form defined by the XRDP found on pages 5 to 7 of the instant specification.

The breadth of the claims

The breadth of the claims is the preparation of any polymorph with any XRDP of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea.

The quantity of experimentation needed and the level of the skill in the art

The quantity of experimentation is extremely high. One would need to prepare crystalline compounds of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea by many different methods to obtain any polymorph of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea while the specification only provides methods and direction to the process of the preparation of the specific crystalline form of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea with the XRDP found on pages 5 to 7 of the instant specification. The level of skill in the polymorph art is high. However, without a showing or guidance as to how to make any polymorph, besides the specific crystalline form of pages 5 to 7 as described in the specification, it would require undue experimentation to figure out how to prepare any polymorph from the claimed process.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is again noted that while claim 6 contains the XRDP for "the pure polymorph" of (I), claims 1, 4 and 5, from which claim 6 depends, are not preparing "the pure polymorph" of (I) but "a polymorph" of (I). Therefore, claim 6 is also rejected.

According to Brittain,

For routine work...one typically compares the powder pattern of the analyte to that of reference materials to establish polymorphic identity. Since every compound produces its own characteristic powder diffraction pattern owing to the unique crystallography of its structure, powder X-ray diffraction is clearly the most powerful and fundamental tool for a specification of the polymorphic identity of the analyte. Moreover, the USP general chapter on X-ray diffraction states that the identity is established if the scattering angles of the ten strongest reflections obtained for an analyte agree to within ± 0.20 degrees with that of the reference material, and if the relative intensities of these reflections do not vary by more than 20 percent. (see Brittain in Polymorphism in Pharmaceutical Solids, p.236).

Claims 1-6 fail to recite any X-ray diffraction peaks or recite a minimum of 10 peaks. The recitation of no peaks or less than 10 peaks is not specific enough to particularly point out and distinctly claim the product that Applicant regards as his invention. The claims do not conform to the general practice in the art according to Brittain, i.e. including at least data for the 10 strongest peaks. Claims 1-6 do not contain any of the physical data that particularly points out and distinctly claims the product that Applicant regards as prepared by his invention, i.e. no claim provides at least the 10 strongest peaks of the X-ray diffraction data. For example, without this physical data, it is impossible to distinguish applicants

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crystalline form prepared by the claimed process from any other crystalline form of the prior art, since there is no data in the claims to distinguish applicants' crystalline form from any other crystalline form. It is suggested that the claims be amended to include at least 10 of the strongest peaks of the x-ray diffraction data for the crystalline form of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea prepared by the instant process. However additional data such as the chemical name of the compound melting temperature, DSC thermogram data and infrared spectrum data supported in the instant specification could also be included in order to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to the chemical name of "a polymorph of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea", it is noted that while the inventor may be his/her own lexicographer, claims 1-6 do not contain any of the physical data that particularly points out and distinctly claims the product as prepared by the claimed process that Applicant regards as his invention, i.e. no claim provides at least the 10 strongest peaks of the X-ray diffraction data for the specific crystalline form of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea prepared by applicants' claimed process. "A polymorph of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea" is not a limiting element and does not define a

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difference in the crystalline form of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea. It is the XRDP data that distinguishes applicants' invention from the prior art and not the term "a polymorph of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphthalene-1-yl]-urea". For example, without XRD data in the claims, it is impossible to distinguish applicants crystalline form from any other crystalline form of the prior art, since there is no data in the claims to distinguish applicants' crystalline form prepared from any other crystalline form of the compound.

Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the term "pure" is considered indefinite as it is unclear what amount of the specific polymorph with the XRDP found on pages 5-7 is found in the final product. While the specification provides a definition for "essentially pure" on page 3 of the specification, there is no definition provided for "pure". Is a "pure" polymorph more pure or less pure than an "essentially pure" polymorph? This rejection could be overcome by amending all instances of "pure" in the claims to "essentially pure".

Claims 4 and 6 recite the limitation "the pure polymorph". There is insufficient antecedent basis for this limitation in the claim as there is no "a pure polymorph" found in claim 1 from which claim 4 depends, nor is there mention of "a pure polymorph" in claim 4. Furthermore, there is no mention of "a pure polymorph" in claim 1, 4 or 5 from which claim 6 depends. Therefore, claims 4

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and 6 are indefinite as it is unclear what "pure polymorph" applicant is referring back to with "the pure polymorph". It is suggested that if applicant intends to claim a process for the preparation of an essentially pure polymorph of formula (I) with the XRDP as found on pages 5-7 of the instant specification, applicant amend the claims to read: "a process for the preparation of an essentially pure compound of 1-[tert-butyl-1-p-tolyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-ylethoxy)naphthalen-1-yl]-urea (1) with the XRDP of ..."

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,319,921. US Patent No. 6,319,921 discloses the process for preparing the compound 8, column 49, which corresponds to the compound prepared by applicants' instant process. Column 49 states that the product LXXXIX, was reacted with LXVII from example 1 according to method B to provide 8. Referring back to example 1, method B, LXVII is reacted and the solid is recrystallized with water and ethanol.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,319,921.

Determining the scope and contents of the prior art

US Patent No. 6,319,921 discloses the process for preparing the compound 8, column 49, which corresponds to the compound prepared by applicants' instant process. Column 49 states that the product LXXXIX, was reacted with LXVII from example 1 according to method B to provide 8.

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Referring back to example 1, method B, LXVII is reacted and the solid is recrystallized with water and ethanol.

Ascertaining the differences between the prior art and the claims at issue.

The difference between the prior art and the claims at issue is that the prior art does not specify the amount of ethanol or the temperature of the reaction. Also, the indefinite pure polymorph, such as with the XRDP of claim 6, is not described in the prior art reference. However, the prior art reference does prepare a crystalline form of the same chemical substance.

Furthermore, The difference between the prior art and the instant claims 4 and 6 is that the X-ray diffraction pattern the crystalline solid of the prior art may differ from that of the X-ray diffraction pattern of the instant claims "pure polymorph". However, Brittain taught that "in the strictest sense, polymorphs are different crystalline forms of the same pure substance in which the molecules have different arrangements and/or different conformations of the molecules (see Brittain p. 1-2).

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art to prepare any polymorph of 1-[tert-butyl-1-p-toyly-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphalen-1-yl]-urea by crystallizing in ethanol with a specific temperature or weight of ethanol or with the presence of a pure polymorph as the Courts have decided per *In re Boesch*, 205 USPQ 215 (1980), that the optimization of variables, such as pH and molar ratios, in a known process is prima facie obvious. Therefore, the claimed

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process would have been suggested to one skilled in the art. Furthermore, mere difference in physical property is well known conventional variation for the same pure substance (see Brittain p. 1-2), i.e. prima facie obvious.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,319,921 and WO 01/04115.

Determining the scope and contents of the prior art

US Patent No. 6,319,921 discloses the process for preparing the compound 8, column 49, which corresponds to the compound prepared by applicants' instant process. Column 49 states that the product LXXXIX, was reacted with LXVII from example 1 according to method B to provide 8. Referring back to example 1, method B, LXVII is reacted and the solid is recrystallized with water and ethanol.

WO 01/04115 discloses the process of preparing the compound of the formula (I) on page 18, by reacting 4-amin-1-(2-morpholinethoxy)naphthalene with 5-(2,2,2-trichloroethoxycarbonyl)amino-2-tert-butyl-1-p-tolylpyrazole in the presence of a secondary amine and a solvent consisting of DMSO and ethyl acetate, see pages 19 and 20.

Ascertaining the differences between the prior art and the claims at issue.

The difference between the prior art and the claims at issue is that the prior art does not specify the specific molar ratios as claimed. Also, the indefinite pure polymorph, such as with the XRDP of claim 6, is not described in the prior art reference. However, the prior art reference does prepare a crystalline form of the same chemical substance.

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Furthermore, The difference between the prior art and the instant claims is that the X-ray diffraction pattern the crystalline solid of the prior art may differ from that of the X-ray diffraction pattern of the instant claims. Brittain taught that "in the strictest sense, polymorphs are different crystalline forms of the same pure substance in which the molecules have different arrangements and/or different conformations of the molecules (see Brittain p. 1-2).

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art to prepare any polymorph of 1-[tert-butyl-1-p-toyly-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphalen-1-yl]-urea by crystallizing in ethanol with a molar ratio of the compounds found in WO 01/04115 as the Courts have decided per In re Boesch, 205 USPQ 215 (1980), that the optimization of variables, such as pH and molar ratios, in a known process is prima facie obvious. Therefore, the claimed process would have been suggested to one skilled in the art. Furthermore, mere difference in physical property is well known conventional variation for the same pure substance (see Brittain p. 1-2), i.e. prima facie obvious.

Conclusion

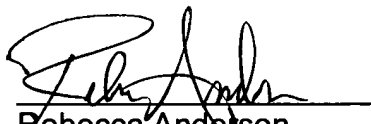
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Rebecca Anderson
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Art Unit 1626, Group 1620
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May 30, 2006